NOSE RIDER IMPROVEMENT FOR FILTER EXCHANGE AND METHODS OF USE

Field of the Invention

The present invention relates generally to the field of embolic protection devices. More specifically, the present invention pertains to systems and methods for transporting and exchanging intravascular devices within a body lumen.

Background of the Invention

Guidewires are frequently used to advance intravascular devices to various locations within the body such as an artery or vein. Examples of therapeutic procedures employing such devices include percutaneous transluminal coronary angioplasty (PTCA), percutaneous extraction atherectomy, and stent placement. In a PTCA procedure, for example, a guidewire is percutaneously inserted into a patient's body, and then advanced to a target site where a stenosis or other occlusion is located. Once in place, an angioplasty catheter having an inflatable balloon is advanced along the guidewire and positioned across the site of the stenosis to be dilated. The inflatable balloon is then inflated, causing some embolic material to dislodge from the wall of the vessel and flow downstream.

To prevent the escape of embolic material dislodged during the therapeutic procedure, an embolic protection filter can be advanced to a location distal the target site and deployed to capture emboli present within the blood stream. These devices typically comprise a support structure coupled to a filter mesh or membrane that captures embolic material such as plaque and thrombus, while permitting the perfusion of blood through the vessel. The embolic protection filter may be configured to self-deploy within the

vessel when actuated, and may be configured to radially collapse within a catheter or other delivery device to facilitate transport through the body.

During interventional vascular procedures such as angioplasty, atherectomy, thrombectomy and stenting, access to the lesion is often exacerbated due to the tortuous nature of the vasculature. To access the site of the lesion to be treated, the physician may advance an elongated wire such as a guidewire to a location within the vessel distal the lesion. Such guidewires are typically 0.014 inches in diameter, and vary in stiffness along their length. Since such guidewires often have a relatively small profile in comparison to other intravascular devices such as angioplasty catheters or stent delivery catheters, the ability to advance an intravascular device across the site of the lesion may be improved by using more conventional guidewires.

Summary of the Invention

The present invention relates generally to the field of embolic protection devices. More specifically, the present invention pertains to systems and methods for transporting and exchanging intravascular devices within a body lumen. In one exemplary embodiment of the present invention, a filter system comprises a filter wire assembly and a filter delivery device. The filter wire assembly includes a guide tip and embolic protection filter disposed about an elongated wire. The guide tip has a proximal portion, a distal portion, and a guidewire lumen adapted to receive a guidewire. In certain embodiments, the embolic protection filter and guide tip can be formed on a single frame from one or more members and/or materials. The frame may include a coil or slotted tube, and may include a port configured to slidably receive a guidewire.

The guide tip may be tapered such that proximal portion has a relatively larger profile than the distal portion. In some embodiments, the guidewire lumen disposed within the guide tip may be substantially straight. In other embodiments, the guidewire lumen may include a curved region. In either embodiment, the guidewire lumen may include a polymeric coating to provide a smooth, lubricious interior surface for the guidewire. Moreover, the guide tip may include a radiopaque marker band, a spring coil, or an atraumatic distal tip, if desired.

A filter delivery device in accordance with an exemplary embodiment of the present invention may include an elongated tubular member extending distally to a distal sheath. A first lumen disposed within the distal sheath is adapted to receive the elongated wire. A second lumen disposed within the distal sheath is adapted to receive the guidewire.

The distal sheath may be dimensioned such that the proximal portion of the guide tip fits at least in part within the filter delivery device. In some embodiments, the distal sheath may include a key adapted to slide within a corresponding groove formed on the proximal portion of the guide tip. The key and groove ensure proper radial alignment of the guidewire lumen with the first lumen of the filter delivery device. In other embodiments, the shape of the guide tip and/or distal sheath can be configured to ensure proper radial alignment of the guidewire lumen with the first lumen.

The filter delivery device may include one or more skived regions located along the length of the distal sheath. These skived regions reduce the net frictional force exerted by the guidewire, and reduce the profile of the device to facilitate advancement through the vascular system. If desired, a loading tool can be used to thread the

guidewire through the filter delivery device. A longitudinal slit spanning the length of the loading tool can be used to remove the loading tool from the skived region once the guidewire has been inserted into the guide tip and filter delivery device.

Once the filter wire assembly is loaded into the filter delivery device and advanced along the guidewire to a location distal a lesion, the guidewire can then be removed from the body. The filter delivery device can then be withdrawn proximally, causing the embolic protection filter to exit the distal sheath and expand within the vessel. A therapeutic device such as an angioplasty catheter can then be advanced along the filter wire to perform the therapeutic procedure. The embolic protection filter can then be collapsed and removed via a multiple-lumen retrieval sheath having a filter retrieval lumen and a guidewire lumen. If desired, a second guidewire contained in the retrieval sheath can be placed within the vessel. A longitudinal slit extending distally from the proximal end of the retrieval sheath can be used to remove the retrieval sheath from the second guidewire.

Brief Description of the Drawings

Figure 1 is a perspective view of a filter wire assembly in accordance with an exemplary embodiment of the present invention, wherein the filter wire assembly includes an embolic protection filter and guide tip attached to an elongated wire;

Figure 2 is a cross-sectional view of the guide tip illustrated in Figure 1, wherein the distal end of the elongated wire includes a protrusion configured to provide an interference fit with the guide tip;

Figure 3 is a cross-sectional view of another guide tip in accordance with an exemplary embodiment of the present invention, wherein the guide tip includes a substantially straight guidewire lumen;

Figure 4 is a cross-sectional view of the proximal portion of a guide tip in accordance with another exemplary embodiment of the present invention, wherein the guide tip includes a guidewire lumen having a curved region;

Figure 5 is a partial cross-sectional view of a filter wire assembly in accordance with an exemplary embodiment of the present invention, wherein the filter and guide tip are formed on a single frame;

Figure 6 is a partial cross-sectional view of a filter wire assembly in accordance with another embodiment of the present invention, wherein the filter frame includes a stopper mechanism;

Figure 7 is a cross-sectional view showing the filter wire assembly of Figure 6 along line 7-7;

Figure 8 is a perspective view of a filter wire assembly in accordance with another exemplary embodiment of the present invention, wherein the filter frame and proximal support hoop comprise a single coil;

Figure 9 is a perspective view of a filter frame in accordance with another exemplary embodiment of the present invention, wherein the filter frame includes a slotted tubular member;

Figure 10 is a perspective view of a filter frame in accordance with another exemplary embodiment, wherein the filter frame includes a slotted tubular member having multiple slotted sections;

Figure 11 is a perspective view of a filter frame in accordance with another exemplary embodiment, wherein the filter frame includes a slotted tubular member having multiple slotted sections;

Figure 12 is a perspective of a filter frame in accordance with another exemplary embodiment, wherein the filter frame includes a slotted tubular member having a multiple slotted sections and a guidewire port;

Figure 13 is a partial cross-sectional view of a filter wire assembly in accordance with another embodiment of the present invention;

Figure 14 is a perspective view of a filter delivery device in accordance with an exemplary embodiment of the present invention;

Figure 15 is a cross-sectional view showing the filter delivery device of Figure 14 along line 15-15;

Figure 16 is a perspective view of the filter delivery device of Figure 14, wherein the filter wire assembly of Figure 1 is shown inserted through the delivery device;

Figure 17 is a cross-sectional view of the filter system of Figure 16, wherein the filter wire assembly is inserted at least in part within the distal sheath;

Figure 18 is a cross-sectional view of a filter delivery system in accordance with another exemplary embodiment of the present invention, wherein the distal sheath includes a key configured to slide within a corresponding groove formed on the proximal portion of the guide tip;

Figure 19 is another cross-sectional view showing the filter delivery system of Figure 18 along line 19-19;

Figure 20 is a perspective view of a filter delivery device in accordance with another exemplary embodiment of the present invention, wherein the filter delivery device includes a skived region;

Figure 21 is a perspective view of a filter delivery device in accordance with yet another exemplary embodiment of the present invention having a skived region;

Figure 22 is a perspective view of a filter delivery device in accordance with an exemplary embodiment of the present invention, wherein the filter delivery device includes several skived regions;

Figure 23 is a perspective view of a loading tool in accordance with an exemplary embodiment of the present invention;

Figure 24 is a cross-sectional view showing the loading tool of Figure 23 along line 24-24;

Figure 25 is another perspective view of the loading tool of Figure 23, wherein the loading tool is shown inserted into the guide tip and filter delivery device;

Figure 26 is yet another perspective view of the loading tool of Figure 23, wherein the loading tool is inserted into the guide tip and filter delivery device, and the guidewire is inserted through the device;

Figure 27 is a perspective view of loading tool of Figure 23, wherein the loading tool is shown being removed from the guidewire;

Figure 28 is a perspective view of a loading member in accordance with an alternative embodiment of the present invention, wherein the loading member is placed across a skived region on the filter delivery device;

Figure 29 is a plan view of a guidewire inserted into a vessel at a location distal a lesion;

Figure 30 is a plan view of a filter delivery device and filter wire assembly advanced to the distal portion of the guidewire illustrated in Figure 29;

Figure 31 is a plan view of the filter delivery system of Figure 30, wherein the guidewire has been withdrawn;

Figure 32 is another plan view of the filter system of Figure 30, wherein the filter delivery device has been withdrawn, and wherein the embolic protection filter is in a deployed state;

Figure 33 is a plan view illustrating a therapeutic device advanced along the filter wire to the site of the lesion;

Figure 34 is a plan view illustrating a retrieval sheath in accordance with an exemplary embodiment of the present invention, wherein the retrieval sheath contains a second guidewire, and wherein the embolic protection filter is collapsed at least in part within the retrieval sheath;

Figure 35 is a cross-sectional view showing the retrieval sheath of Figure 34 along line 35-35;

Figure 36 is a perspective view of a retrieval sheath in accordance with another exemplary embodiment of the present invention, wherein the retrieval sheath includes an opening for single operator exchange of the second guidewire;

Figure 37 is a cross-sectional view showing the retrieval sheath of Figure 36 along line 37-37;

Figure 38 is a cross-sectional view showing the retrieval sheath of Figure 37 along line 38-38;

Figure 39 is a cross-sectional view showing the retrieval sheath of Figure 37 along line 39-39;

Figure 40 is a cross-sectional view showing the retrieval sheath of Figure 37 along line 40-40;

Figure 41 is a view of the retrieval sheath illustrated in Figures 36-40, wherein the retrieval sheath is shown advanced to a desired location within a body lumen, and wherein the retrieval sheath is loaded with a second guidewire;

Figure 42 is a perspective view of a retrieval sheath in accordance with another exemplary embodiment of the present invention configured for single operator exchange;

Figure 43 is a cross-sectional view showing the retrieval sheath of Figure 42 along line 43-43;

Figure 44 is a cross-sectional view showing the retrieval sheath of Figure 43 along line 44-44;

Figure 45 is a cross-sectional view showing the retrieval sheath of Figure 43 along line 45-45;

Figure 46 is a cross-sectional view showing the retrieval sheath of Figure 43 along line 46-46; and

Figure 47 is a cross-sectional view showing the retrieval sheath of Figure 47 along line 47-47.

Detailed Description of the Invention

The following description should be read with reference to the drawings, in which like elements in different drawings are numbered in like fashion. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. Although examples of construction, dimensions, materials and manufacturing processes are illustrated for the various elements, those skilled in the art will recognize that many of the examples provided have suitable alternatives that may be utilized.

Figure 1 is a perspective view of a filter wire assembly 10 in accordance with an exemplary embodiment of the present invention. Filter wire assembly 10 includes an elongated wire 11, an embolic protection filter 12, and a guide tip 13. Elongated wire 11 has a proximal end 14 and a distal end 15. As is discussed in greater detail below, filter wire assembly 10 is adapted to attach to a filter delivery device which, in turn, can be utilized to transport the filter wire assembly 10 to a desired location within a patient's body.

Elongated wire 11 can be constructed of any suitable material(s) biocompatible with the body. Examples of such materials include 304 or 316 grade stainless steel, platinum, or nickel-titanium alloy (Nitinol). Nickel-titanium alloy exhibits super-elastic capabilities at body temperature (approximately 37°C), which permits substantial bending or flexing with a relatively small amount of residual strain. It is contemplated, however, that other materials can be used. For example, in some embodiments, elongated wire 11 may comprise a stainless steel core wire surrounded by a polymeric coating to facilitate smooth transport of other intravascular devices thereon.

The embolic protection filter 12 may include a filter mesh or membrane 16 operatively coupled to a wire 17 that forms a suspension arm 18 and a support hoop 19. The wire 17 may comprise a shape-memory material such as a nickel-titanium alloy, allowing the support hoop 19 to bend and flex while maintaining its original shape.

A radiopaque coil 20 helically disposed about the support hoop 19 can be used to fluoroscopically judge the placement and deployment status of the embolic protection filter 12 within the patient. Coil 20 may be formed of a relatively high radiopaque material such as gold, platinum or tantalum, which can be utilized in conjunction with a fluoroscopic monitor to determine an accurate measure of the location of the embolic protection filter 12 within the vasculature.

The proximal end 21 of wire 17 can be attached to a first tubular member 22 disposed about the elongated wire 11, as shown in Figure 1. Alternatively, the proximal end 21 of wire 17 can be attached directly to the elongated wire 11. Attachment of wire 17 to either the first tubular member 22 or directly to elongated wire 11 can be accomplished by any suitable attachment means such as adhesive, brazing, soldering, welding, crimping or any combination(s) thereof.

In the embodiment illustrated in Figure 1, embolic protection filter 12 is further coupled at a distal section 23 to a second tubular member 24 slidably and rotationally disposed about elongated wire 11 distal the first tubular member 22. Second tubular member 24 has an inner diameter slightly larger than the outer diameter of the elongated wire 11, allowing the second tubular member 24 to move thereon. In an alternative embodiment (not shown), the distal section 23 of embolic protection filter 12 can be attached directly to the elongated wire 11. When attached directly to the elongated wire

11, the distal section 23 of embolic protection filter 12 is substantially prevented from moving along the elongated wire 11.

Filter wire assembly 10 may further include a guide tip 13. Guide tip 13 has a proximal portion 25, a distal portion 26, and a guidewire lumen 27 therethrough. Guidewire lumen 27 may include a polymeric liner such as polytetrafluoroethylene (PTFE) to provide a smooth, lubricious interior surface for a second wire.

As shown in Figure 1, the distal end 15 of elongated wire 11 may be attached to the proximal portion 25 of guide tip 13 at joint 28. Elongated wire 11 can be attached to the guide tip 13 at joint 28 by, for example, molding the proximal portion 25 of guide tip 13 over the distal end 15 of elongated wire 11. Alternatively, elongated wire 11 can be attached to guide tip 13 by means of a shrink-fit, adhesive, soldering, welding, crimping, or other suitable attachment means.

In one exemplary embodiment illustrated in Figure 2, the distal end 15 of elongated wire 11 may include attachment means configured to provide an interference fit with joint 28 of guide tip 13. The attachment means may comprise a coil 29 disposed about the distal end 15 of the elongated wire 11 having an outer diameter that is slightly larger than the inner diameter of the joint 28. Elongated wire 11 can be attached to the proximal portion 25 of guide tip 13 by advancing the distal end 15 into joint 28 with sufficient force to overcome the interference fit. A reduced inner diameter portion 30 on the joint 28 prevents the distal end 15 of elongated wire 11 from detaching from the guide tip 13 once the distal end 15 of the elongated wire 11 is inserted into the joint 28.

Guide tip 13 is further configured in size and shape to facilitate advancement of the filter wire assembly 10 through the patient's body. For example, in the exemplary

embodiment illustrated in Figure 2, the guide tip 13 includes a tapered profile such that the proximal portion 25 of guide tip 13 has a larger profile than the distal portion 26 of guide tip 13.

Referring now to Figure 3, a guide tip 113 in accordance with an alternative embodiment of the present invention will now be described. Guide tip 113 includes a proximal portion 125, a distal portion 126, and a guidewire lumen 127. Guide tip 113 has a tapered profile such that the proximal portion 125 of guide tip 113 is relatively larger than the distal portion 126 of guide tip 113. The guidewire lumen 127 of guide tip 113 is substantially straight, extending distally from a port 131 disposed on the proximal portion 125 of the guide tip 113 to a port 132 disposed on the distal portion 126 of guide tip 113. As with the previous embodiment, guidewire lumen 127 is adapted to receive a guidewire therethrough.

A tapered hole 133 disposed on the proximal portion 125 of guide tip 113 can be used to attach the distal end 15 of elongated wire 11 to the proximal portion 125 of guide tip 113. Tapered hole 133 includes a tapered inner diameter that facilitates insertion of the distal end 15 of elongated wire 11 into tapered hole 133. The proximal portion 125 of guide tip 113 can be crimped to attach the elongated wire 11 to the guide tip 113, and, if desired, may be set with an adhesive, solder or other attachment means.

Guide tip 113 further includes a radiopaque marker band 134 placed on the distal portion 126 of guide tip 113. Radiopaque marker band 134 includes a radiopaque material (*e.g.* platinum, gold, tantalum, tungsten, etc.) that can be used by the operator to fluoroscopically judge the location of the guide tip 113 when placed within the vasculature.

The distal portion 126 of guide tip 113 may also be spring-loaded in order to provide greater flexibility and steering during transport within the body. A spring coil 135 can be formed integral with the distal portion 126 of guide tip 113, or can be helically wound about the distal portion 126 of the guide tip 113. If desired, spring coil 135 may be formed of a radiopaque material to act as a radiopaque marker, either alone or in combination with radiopaque marker band 134.

To reduce tissue damage during placement, the distal portion 126 of guide tip 113 may further include an atraumatic distal tip 136. Distal tip 136 may include a relatively soft, atraumatic material (*e.g.* a low-absorption thermal plastic) that is adapted to deform when compressed against the wall of the vessel. This deformation prevents the guide tip 113 from penetrating the vessel wall.

In another exemplary embodiment illustrated in Figure 4, a guide tip 213 in accordance with the present invention may include a guidewire lumen 227 having a curved portion 237. As shown in Figure 4, guidewire lumen 227 extends from the distal end (not shown) on the guide tip 213 proximally to a point located on the proximal portion 225 of guide tip 213. At portion 237, the guidewire lumen 227 curves slightly, terminating at port 231. As with the embodiment illustrated in Figure 3, guide tip 213 may include a tapered hole 233 for insertion of the distal end 15 of elongated wire 11, and may include a radiopaque marker band, spring coil and/or atraumatic distal tip.

Figure 5 is a partial cross-sectional view of a filter wire assembly 310 in accordance with an exemplary embodiment of the present invention, wherein the embolic protection filter 312 and guide tip 313 are formed on a single frame 338. Frame 338 comprises proximal section 339, a middle section 340, and a distal section 341. Frame

338 further defines an inner lumen 327 configured to slidably receive a second guidewire 2 through a port 342. The proximal section 339 of frame 338 can be mounted to the distal end 15 of elongated wire 11.

The distal section 341 of frame 338 has an enlarged outer diameter, forming a guide tip 313. Guide tip 313 includes a proximal portion 325 and a distal portion 326. The guide tip 313 is tapered such that the proximal portion 325 of guide tip 313 is larger than the distal portion 326 of guide tip 313. In use, guide tip 313 is configured in size and shape to facilitate advancement of the filter wire assembly 310 through the vasculature.

The frame 338 can be formed from an injection mold process utilizing a suitable polymeric material such as polypropylene (PP) or polyvinylchloride (PVC). In other embodiments, the frame 338 may be formed from different members and/or materials that are coupled together. For example, the proximal and distal sections 339,341 of frame 338 may be formed of a polymeric member, whereas the middle section 340 of frame 338 may comprise a coil or slotted hypotube. The various sections of the frame 338 can be bonded together by adhesive, welding, crimping, soldering, insert molding, or other suitable bonding technique.

Figure 6 is a partial cross-sectional view of a filter wire assembly 410 in accordance with another exemplary embodiment of the present invention, wherein the filter frame 438 includes a stopper mechanism 474. Similar to the embodiment illustrated in Figure 5, the embolic protection filter 412 and guide tip 413 are formed on a single frame 438 having an inner lumen 427 configured to slidably receive a second guidewire 2. The proximal section 439 of filter frame 438 may be formed integral with the distal

end 15 of the elongated wire 11, as shown in Figure 6, or can be formed as separate elements similar to that depicted in Figure 5. Visual indicator means such as a spiral-shaped stripe 475 may be employed to permit the user to visually differentiate between the elongated wire 11 and the guidewire 2.

The guide tip 413 may be tapered such that the proximal portion 425 of guide tip 423 is larger than the distal portion 426 of guide tip 413. In use, the embolic protection filter 412 and guide tip 413 are configured to fit within a delivery sheath 476 for transport through the patient's body. As shown in Figure 7, the delivery sheath 476 may include a longitudinal slit 477 along its length allowing the operator to peel-away the delivery sheath 476 from the filter wire assembly 410 once placed at the target site.

Stopper mechanism 474 may include an object attached to the filter frame 438 configured to prevent the user from retracting the filter wire assembly 410 beyond a necked-down section 478 of the delivery sheath 476. As shown in Figure 6, stopper mechanism 474 may include, for example, a wire coil 479 having an outer diameter slightly larger than the inner diameter of the delivery sheath 476 at the necked-down section 478. In use, the wire coil 479 prevents proximal movement of the filter wire assembly 410 beyond the necked-down section 478 of the delivery sheath 476.

Figure 8 is a perspective view of a filter wire assembly 510 in accordance with another exemplary embodiment of the present invention, wherein the filter frame 538 and support hoop 519 are formed of a single coil. Filter frame 538 has a proximal section 539, a distal section 541, and an inner lumen (not shown) configured to slidably receive a guidewire 2. The distal section 541 of filter frame 538 is attached to a guide tip 513 to facilitate advancement of the filter 512 through the vasculature.

The coiled frame 538 may be formed of a metal or metal alloy such as stainless steel or nickel-titanium alloy. The specifications (*e.g.* wire pitch, inner diameter, outer diameter, length, etc.) of the frame 538 can be selected to accommodate to the type of guidewire or filter employed, and the particular location of the body to be traversed.

Figures 9-12 depict other selected embodiments of the present invention wherein the filter frame includes a slotted tubular member. As shown in Figure 9, for example, the slotted tubular member 638 may include a hypotube having a continuous slot or groove 642 helically disposed about a portion of the outer surface of the tubular member 538. The angle, pitch, and width of the slots can be selected to impart a particular flexibility to the tubular member 638, if desired.

In another embodiment illustrated in Figure 10, a slotted tubular member 738 in accordance with the present invention may include multiple sections having differing flexibility characteristics. Tubular member 738 may include a first region 739 having loosely spaced slots 742, a second region 740 distal the first region 739 having slots 742 spaced narrower than at the first region 739, and a third region 741 distal the second region 740 having slots 742 spaced narrower than at the first and second regions 739,740. In use, the three regions 739,740,741 impart variable flexibility along the length of the tubular member 738.

The location and number of regions can be varied depending on the particular performance characteristics desired. For example, in one exemplary embodiment illustrated in Figure 11, the slotted tubular member 838 may include a first region 839 having a loosely spaced slots 842, a third region 841 having tightly spaced slots 842, and a second region 840 having slots 842 that are more loosely spaced than the slots at the

first and third regions 839,841. The arrangement of the three regions 839,840,841 provides a stiffer flexural profile in the middle portion of the tubular member 838.

In certain embodiments, the tubular member 938 may include a port 942, such as that depicted in Figure 12. The port 942 may be configured to slidably receive a guidewire through the inner lumen of the tubular member 938, similar to that described above with respect to Figure 7.

Figure 13 is a partial cross-sectional view of a filter wire assembly 1010 in accordance with another exemplary embodiment of the present invention. Filter wire assembly 1010 comprises a filter frame 1012 including a tubular member 1014 with a proximal end 1016, a distal end 1018, and an inner lumen therethrough 1020 configured to slidably receive a second guidewire 2. The filter frame 1012 may be configured to support an embolic protection filter 1022 including a filter membrane 1024 and a support strut 1026. The proximal end 1028 of the support strut 1026 may be coupled to the tubular member 1014 via a coil 1030 that can be slid over the outer portion of the tubular member 1014 and secured thereto with solder, adhesive or other suitable bonding technique.

An elongated wire 1032 secured to the tubular member 1014 may be used to guide the filter wire assembly 1010 within the body. The elongated wire 1032 can be secured to the tubular member 1014 at one or more attachment locations. As shown in Figure 13, for example, the elongated wire 1032 may be coupled to the tubular member 1014 via coil 1030. The elongated wire 1032 may also be secured at or near its distal end 1034 to a second coil 1036 placed about the distal end 1018 of the tubular member 1014.

In certain embodiments such as that depicted in Figure 13, the elongated wire 1032 may taper in the distal direction to increase the flexibility at the distal end 1034, if desired.

The distal end 1018 of the tubular member 1014 may be coupled to an atraumatic guide tip 1038. Guide tip 1038 includes a proximal portion 1040 and a distal portion 1042. The guide tip 1038 is tapered such that the proximal portion 1040 of the guide tip 1038 is larger than the distal portion 1042 of the guide tip 1038. As with other embodiments described herein, the guide tip 1038 may be configured in size and shape to facilitate advancement of the filter wire assembly 1010 through the vasculature.

Referring now to Figure 14, a filter delivery device 43 in accordance with an exemplary embodiment of the present invention will now be described. Filter delivery device 43 comprises an elongated tubular member 44 having a proximal section 45 and a distal section 46. The distal section 46 of elongated tubular member 44 is flared slightly, forming a distal sheath 47 that is configured to contain an embolic protection filter such as that described with respect to Figure 1. The proximal section 45 of elongated tubular member 44 includes a handle 48 that can be used by the operator to maneuver the filter delivery device 43 through the patient's vasculature.

Elongated tubular member 44 defines a first lumen 49 adapted to receive a wire at a first port 50 located at the distal end 51 of the distal sheath 47. The first lumen 49 extends proximally from first port 50 through the distal sheath 47, and exits the elongated tubular member 44 at a first exit port 52.

Elongated tubular member 44 further defines a second lumen 53 adapted to receive a wire at a second port 54 located at the distal end 51 of the distal sheath 47. The second lumen 53 extends proximally from second port 54 through the distal sheath 47,

and exits the elongated tubular member 44 at a second exit port 55 disposed distal the first exit port 52. As shown in greater detail in Figure 15, the portion of first lumen 49 disposed within distal sheath 47 is substantially circular in shape, and is adapted to receive, in part, an embolic protection filter. The second lumen 53 is also substantially circular in shape, and is adapted to receive a wire.

To load the filter wire assembly 10 into the filter delivery device 43, the operator inserts the proximal end 14 of elongated wire 11 into first port 50, and advances the elongated wire 11 through first lumen 49 until the proximal end 14 of elongated wire 11 exits the first exit port 52, as shown in Figure 16. To collapse the embolic protection filter 12 into the distal sheath 47, the operator continues to feed the elongated wire 11 proximally through the first lumen 49 until the embolic protection filter 12 and a portion of the guide tip 13 are loaded into the distal sheath 47, as shown in Figure 17. Once the embolic protection filter 12 and guide tip 13 are loaded into the distal sheath 47, the operator may, if necessary, align the guidewire lumen 27 of guide tip 13 concentrically with the second lumen 53 of the filter delivery device 43.

In one exemplary embodiment illustrated in Figure 18, the distal sheath 147 may include a key 156 configured to slide within a corresponding groove 57 formed on the proximal portion 25 of the guide tip 13. As shown in cross-section in Figure 19, the key 156 may be configured in size and shape to permit the proximal portion 25 of guide tip 13 to slide within the distal sheath 147 when radially aligned with groove 57. When utilized, the key 156 and groove 57 ensure radial alignment of the guidewire lumen 27 and second lumen 153 to facilitate insertion of a guidewire therethrough. Moreover, the

key 156 and groove 57 may be utilized to prevent radial displacement of the guide tip 13 relative to the distal sheath 147 during placement of the device within the body.

It is to be understood that while a key and groove are utilized in the exemplary embodiment of Figures 18-19, other configurations are possible to ensure radial alignment of the guidewire lumen of the guide tip with the second lumen of the filter delivery device. For example, the proximal portion of the guide tip may include a flat, forming a D-shaped configuration (when viewed from an end) configured to slide within a corresponding flat formed within the distal sheath. In use, the D-shaped configuration permits insertion of the guide tip into the distal sheath when the guidewire lumen of the guide tip is aligned with the second lumen of the filter delivery device.

It is to be further understood that while both the first and second lumens 49, 53 of elongated tubular member 44 are shown extending through the entire length of the distal sheath 47, other configurations have been envisioned. For example, as shown in Figures 20-21, the second port 254, 354 of filter delivery device 243, 343 may terminate at various locations proximal the distal end 251, 351 of the distal sheath 247, 347, forming skived regions 258, 358. These skived regions 258, 358 reduce the net frictional force exerted on the guidewire 11, reduce the crossing profile of the device, and in some embodiments, allow the guide tip 13 to rotate relative to the distal sheath 247, 347 while permitting the guidewire 11 to freely slide through the device.

In one exemplary embodiment shown in Figure 22, the filter delivery device 443 may include several collars 459 that form a plurality of skived regions 458 along the length of the elongated tubular member 444. As with the exemplary embodiments illustrated in Figures 20-21, the skived regions 458 reduce the frictional force exerted on

the guidewire 11, reduce the crossing profile in certain areas along the device 443, and permit the device 443 to bend or flex when advanced through the patient's body.

To thread the guidewire 11 through each skived region, an optional loading tool 60 may be used. As shown in Figures 23-27, a loading tool 60 in accordance with the present invention may include an elongated tubular member 61 configured to slide within the guidewire lumen of the guide tip and the second lumen of the filter delivery device. Loading tool 60 has a proximal end 62, a distal end 63, and an inner lumen 64 configured to slidably receive the elongated wire 11. A longitudinal slit 65 extends along the entire length of the elongated tubular member 61. The distal end 63 of loading tool 60 is flared slightly to facilitate insertion of the elongated wire 11 into the inner lumen 64.

In use, loading tool 60 can be used to insert the elongated wire 11 through any of the aforementioned filter delivery devices and guide tips. As illustrated in Figures 25-27, for example, loading tool 60 can be used to insert elongated wire 11 into the guide tip and filter delivery device combination described with respect to Figure 20. To insert the loading tool 60 into the guide tip 13 and filter deliver device 243, the operator threads the proximal end 62 of the elongated tubular member 61 into guide lumen 27 of guide tip 13, and advances the loading tool 60 across the skived region 258 until the proximal end 62 of the loading tool 60 is disposed within the second lumen 253 of the filter delivery device 243, as shown in Figure 25. Once the loading tool 60 is loaded into the guide tip 13 and filter delivery device 243, the proximal end 14 of the elongated wire 11 is then inserted into the inner lumen 64 of elongated tubular member 61 at the flared distal end 63, and advanced until the proximal end 14 of the elongated wire 11 is located beyond the proximal end 62 of the elongated tubular member 61, as shown in Figure 26. Once

the guidewire 11 has been advanced through the elongated tubular member 61, the loading tool 60 can then be withdrawn from the filter delivery device 243 and guide tip 13. As shown in Figure 27, the elongated wire 11 can be removed from the loading tool 60 vis-à-vis the longitudinal slit 65 located on the elongated tubular member 61. A stylet (not shown) can then be inserted through the inner lumen 64 of elongated tubular member 61 to keep the loading tool 60 stiff for subsequent use.

In an alternative embodiment illustrated in Figure 28, a loading tool 160 in accordance with another exemplary embodiment of the present invention may include a tube segment 161 having longitudinal slit 165 thereon. The length of the tube segment 161 is approximately equal to the length of the skived region 258 such that the loading tool 160 can be temporarily placed across the skived region 258. In use, the loading member 160 allows the operator to more easily thread the elongated wire 11 from the skived region 258 into the second lumen 253 of the filter delivery device 243. The longitudinal slit 165 spans the entire length of the tube segment 161, allowing the operator to later remove the loading tool 160 from the skived region 258, if desired.

Methods of using the filter exchange devices of the present invention will now be described in the context of an interventional procedure such as percutaneous transluminal coronary angioplasty (PTCA). In practicing the subject invention, a conventional guidewire 2 having a proximal end (not shown) and a distal end 4 is percutaneously inserted into a patient, and advanced to a desired location within a vessel V distal a lesion L, as shown in Figure 29. Once in place, the filter wire assembly 10 is loaded into the filter delivery device 43, and, if necessary, aligned such that the guidewire lumen 27 of the guide tip 13 is radially aligned with the second lumen 53 of the filter delivery device

43. Once assembled, the operator next inserts the proximal end of the guidewire 2 through the guidewire lumen 27 and second lumen 53, and advances the filter wire assembly 10 and filter delivery device 43 to a location at or near the distal end 4 of the guidewire 2, as shown in Figure 30.

Once the filter delivery device 43 and filter wire assembly 10 are in position distal lesion L, guidewire 2 can then be withdrawn from the filter delivery device 43 and guide tip 13, and removed from the vessel, as shown in Figure 31. To deploy the embolic protection filter 12 within the vessel V, the operator, while holding the elongated wire 11 stationary, retracts the elongated tubular member 44 proximally, causing the embolic protection filter 12 to exit the first lumen 49 and radially deploy within the vessel V, as shown in Figure 32. An interventional device such as an angioplasty catheter 6 can then be advanced along the elongated wire 11 and inflated, causing some of the emboli E to dislodge from the vessel wall and flow downstream, as illustrated in Figure 33.

To retrieve the filter wire assembly 10 from vessel V, a multiple-lumen retrieval sheath 66 containing a second guidewire 8 can be advanced along the elongated wire 11 to retrieve the embolic protection filter 12. As shown in Figure 34, the second guidewire 8 can be advanced within the vessel V to the same location of the elongated wire 11 used to transport the filter delivery device 43 and filter wire assembly 10. As shown in cross-section in Figure 35, retrieval sheath 66 includes a first lumen 67 adapted to receive elongated wire 11, embolic protection filter 12, and the proximal portion 25 of the guide tip 13. A second lumen 68 disposed within the retrieval sheath 66 is adapted to receive the second guidewire 8. A longitudinal slit 73 extending distally from the proximal end

of retrieval sheath 66 allows the retrieval sheath 66 to be removed from the second guidewire 8.

In an alternative embodiment illustrated in Figures 36-41, a multiple-lumen retrieval sheath 166 may be configured to permit single operator exchange of filter wire assembly 10 with the second guidewire 8 within the body. Retrieval sheath 166 includes a first lumen 167 adapted to receive, for example, the elongated wire 11, embolic protection filter 12, and the proximal portion 25 of guide tip 13 described above with respect to Figure 1. The first lumen 167 extends distally from a first port 168 to the distal end 169 of the retrieval sheath 166. A second lumen 170 extends from the proximal end 171 of the retrieval sheath 166 to a second port 172 disposed on the retrieval sheath 166. The location of port 172 can be either proximal the distal end 169 of the retrieval sheath 166, as shown in Figures 36-37, or can be located at the distal end 169 of the retrieval sheath 166 (not shown). A longitudinal slit 173 extending along the entire length of the second lumen 170 is configured to allow the retrieval sheath 166 to be removed from the second guidewire 8.

To retrieve the filter wire assembly 10 from the body, the proximal end 14 of the elongated wire 11 is inserted into the first lumen 167 at the distal end 169 of the retrieval sheath 166, and is then advanced proximal the first port 168. Holding the elongated wire 11 stationary, the operator next advances the retrieval sheath 166 over the elongated wire 11 to capture the filter wire assembly 10 within the first lumen 167. The second guidewire 8 can be loaded into the second lumen 170 of the retrieval sheath 166, and advanced to a desired location within vessel V. The retrieval sheath 166 can then be removed from the patient's body by pulling the second guidewire 8 through the

longitudinal slit 173 and holding second guidewire 8 steady while withdrawing the retrieval sheath 166 and filter wire assembly 10 from the vessel, as shown in Figure 41.

In an alternative embodiment illustrated in Figures 42-47, a multiple-lumen retrieval sheath 266 configured for single operator exchange of a filter wire assembly (*e.g.* filter assembly 10) may include a first lumen 267 adapted to receive, for example, the elongated wire 11, embolic protection filter 12, and guide tip 13 described above with respect to Figure 1. The first lumen 267 may extend distally from a first port 268 to the distal end 269 of the retrieval sheath 266. The first port 268 may be formed by removing a portion of the outer wall of the retrieval sheath 266, creating a groove 280 in the retrieval sheath 266 that exposes an offset portion 281 of the first lumen 267. As shown in Figure 47, the portion of first lumen 267 extending from the first port 268 to a flared distal sheath 282 may have a substantially rectangular shape with rounded edges. At the flared distal sheath 282, the inner diameter of the first lumen 267 assumes a substantially circular shape configured to receive the embolic protection filter 12 and a portion of the guide tip 13.

A second lumen 270 extending from the proximal end 271 of the retrieval sheath 266 to a second port 272 disposed on the retrieval sheath 266 proximal the first port 268 may be configured to receive an exchange wire such as second guidewire 8 described herein. A longitudinal slit 273 extending distally from the proximal end 271 of the retrieval sheath 266 to a location 283 proximal the second port 272 may be configured to permit the retrieval sheath 266 to be removed from the second guidewire 8 in a manner similar to that described above with respect to Figure 41.

Having thus described the several embodiments of the present invention, those of skill in the art will readily appreciate that other embodiments may be made and used which fall within the scope of the claims attached hereto. Numerous advantages of the invention covered by this document have been set forth in the foregoing description. Changes may be made in details, particular in matters of size, shape, and arrangement of parts without exceeding the scope of the invention. It will be understood that this disclosure is, in many respects, only illustrative.